Philip Morris, USA/MDS PS Meeting

1. Purpose

The purpose of this site visit is three-fold: 1) to have an opportunity of making direct contact with the MDS scientist who are working on Philip Morris projects; 2) to review the quality system of the analytical facility of MDS PS for compliance with Good Laboratory Practice Standards; 3) to review Philip Morris bioanalytical projects and to verify these projects are being conducted in a manner that complies with the GLP standards.

2. Outlines of Procedures

2.1 Review the Quality System

The facility will be reviewed for compliance with the following GLP elements:

Organization and Personnel:	Personnel, management, study director, quality assurance unit
Facility:	Adequateness
Equipment:	Maintenance and calibration records
Operation:	Standard Operating Procedures (SOP) Reference standards characterization Sample receiving and handling
Protocol and Conduct of study:	Written protocols Conduct of study Deviation from protocol
Records and Reports:	Report storage Retrieval of records Data retention

2.2 Review Philip Morris bioanalytical projects

Analytical batches, including the validation and sample analysis batches if available), will be reviewed. The records of batch information, chain of custody, documentation of any deviation from the SOPs, reporting of the results, etc, are of particular interest.

(1) validation to production transition.

(2) ext. procedures changes to 1-024-P SOP

Source: https://www.industrydocuments.ucsf.edu/docs/hjnx0001